



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0500]

Guidance for Industry: Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information " dated February 2012. The guidance provides certain Investigational New Drug Application (IND) sponsors with recommendations in connection with the submission of INDs for early clinical trials with live biotherapeutic products (LBPs). The guidance announced in this notice finalizes the draft guidance of the same title dated September 2010.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information" dated February 2012. The guidance provides certain IND sponsors with recommendations in connection with IND submissions for early clinical trials for LBPs in the United States. The guidance focuses on the chemistry, manufacturing, and control information that should be provided in an IND for early clinical trials evaluating LBPs. The guidance is applicable to INDs of LBPs, whether clinical trials are conducted commercially, in an academic setting, or otherwise.

In the Federal Register of October 14, 2010 (75 FR 63188), FDA announced the availability of the draft guidance of the same title dated September 2010. FDA received a few comments on the draft guidance and those comments were considered as the guidance was

finalized. In response to comments, changes incorporated in the final guidance include the addition of text related to the scope, definitions and background section of the guidance. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 2010.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under 0910-0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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